PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 3024-114

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on July 6, 2010

Signature /Joyce v. Natzmer/

Typed or printed name Joyce von Natzmer

Application Number	Filed
10/555,244	October 31, 2005

First Named Inventor: Miller

Art Unit	Examiner
1651	Kade Ariani

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

Applicant notes that the after final amendment of June 14, 2010 was entered per Advisory Action of July 2, 2010.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 48120.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Joyce v. Natzmer/
Signature

Joyce H. A. von Natzmer
Typed or printed name

301-657-1282
Telephone number

July 6, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 2 forms are submitted.

No *prima facie case* of obviousness was presented to support that claims 1-25, 28-33 and 35 to 40 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5, 569,458 to Greenberg ("Greenberg") in view of Shahid et al. (J Assoc Physicians India, 2002, Vol. 50, p.527-531, hereinafter "Sharid") and further in view of Rayman, M. P. (The Lancet, 2000, Vol. 356, p. 233-241) and Vetvicka et al. (JANA, 2002, Vol. 5, No.2, p.5-9) and Ochao et al. (Journal of Parenteral & Enteral Nutrition, 2001, Vol. 25, No. 1, p.23-29) and Birt et al. (Pharmacology & Therapeutics, 2001, Vol. 90, p.157-177) and Jensen et al. (J. Nutr., 1999, Vol. 129, p.1355-1360), and Hughes et al. (The Journal of infectious diseases, 2000, Vol. 182, Suppl. 1, S11-S15).

Claim 1, the only independent claim in this application, is directed at a composition, which comprises, among others, one or more plant protease, and/or one or more animal protease, wherein said one or more plant protease and/ or animal protease are present in a total concentration of 20% to 60% by weight of active constituents in the composition. The composition also contains antioxidants, selenium-containing substances, flavonoids and/or flavonoid-containing substances.

Greenberg discloses a vitamin and mineral formulation which provides for improved absorption of its nutrients by the addition of **digestive enzymes** to the formulation and **including the herb goldenseal to prevent the enzymes from eating up the other nutrients**, giving it the capability to retain its value for up to six months (abstract, first sentence).

The Office has repeatedly acknowledged that Greenberg does not teach that his digestive enzymes (which are considered equivalent to the one or more proteases of the present invention) are present in a **total concentration of 20% to 60% by weight** of active constituents as required by the presently claimed invention.

The Office also acknowledged that Greenberg's formulation does not contain flavonoids/flavonoid –containing substances in the concentrations specified in claims 1 (10% to 50% by weight of active constituents) and that specific embodiments that are claimed in several dependent claims, such as the embodiment specifying that the carotinoid is lycopene, the amino acid is L-argnine etc., are not disclosed by Greenberg.

The Office expressed the opinion that Sharid's enzyme formulation compensates for the specific concentrations of "proteases" missing from Greenberg by teaching an oral enzyme formulation comprising bromalin (90 mg), trypsin (48 mg), rutin (100mg), which amounts, according to the Office's calculation, to 57.9% enzyme (and 42.1% rutin). Notably there are no vitamins and minerals in Sharid's enzyme formulation called PHLOGENZYM.

Nonetheless, the Office concludes in view of these teachings that:

> "a person of ordinary skill in the art at the time the invention was made, knowing that the administration of the proteolytic enzyme formulation (at a total concentration of 20% to 60% by weight) regulates the immune function, would have been motivated to optimize the amount of enzymes and flavonoids in the food composition as taught by Greenberg according to teachings of Shahid et al. with a reasonable expectation of success in order to provide a composition with an improved immune strengthening properties, because Shahid et al. teach oral administration of a proteolytic enzymes formulation (bromelain, trypsin, and rutin, containing 57.9% total enzyme concentration and % 42.1 total flavonoid concentration) regulates the immune function." (*emphasis added- Office Action of March 12, 2010, page 8, last paragraph*)

Thus, in sum, the Office argues that since Sharid provides a proteolytic enzyme formulation with 57.2% enzymes, it would be obvious to adjust the amount of "digestive enzymes" in Greenberg's vitamin and mineral formulation to 20% to 60%.

Greenberg specifically states that in his vitamin and mineral formulation is composed in such a way that

> "the at least one herb, at least one digestive enzyme, and at least one pH balancing substance, together making up no more than approximately 10% of the weight of the nutrition formulation." (*emphasis added,* col. 6, lines 53 to 56)

The reason for the upper limit of 10% becomes clear when reading the remainder of Greenberg's disclosure. Greenberg includes goldenseal specifically into his vitamin and mineral formulation **to prevent the digestive enzymes from "eating up" the other nutrients** (Abstract and col. 3, lines 59 to 66). Greenberg includes digestive enzymes in his formulation to remedy the common dietary supplement problem of low absorbability of nutrients (col. 4, lines 45 to 48). Greenberg also notes, that although the addition of enzymes may not increase its long-term marketability [due to shorter **shelf life**], the formula's increased absorbability of its nutrients greatly increases the effectivity and performance of his invention (paragraph bridging col. 4 and 5).

Applicant submits that the above shows that Greenberg teaches away from a concentration of 20% to 60% for the digestive enzymes. As a result, one of ordinary skill in the art would not modify Greenberg's vitamin and mineral formulation to incorporate the high concentrations of proteases taught for Sharid's enzyme formulation to arrive at the claimed invention (see, MPEP § 2143.03(VI), which states states that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.").

Alternatively or additionally, applicants submit that Greensberg's teachings of the effects of the enzymes on the nutrients in his vitamin and mineral formulation also strongly suggest, that increasing the enzyme concentration in Greenberg's formulation would render his formulation unsatisfactory for its intended purpose, namely to provide vitamins and minerals to a subject. Applciants submit that it is well established that if a proposed modification would render the prior art invention

being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (MPEP 2143.01).

The Office replied only to the last of the two arguments above which have been previously presented and stated on page 13 of the Office Action that "this argument has not been found persuasive because Greenberg teach including enzymes in the dietary supplement aid in absorption of the vitamin and thereby optimizing the bioavailability of the nutrients (col. 4, lines 45 to 50)."

Applicant submits that this position is not fully responsive to applicant's argument.

Applicant has clearly shown that no *prima facie* case of obvious has been established with regard to claims 1 to 25, 28 to 33 and 35 to 40. In view of this, an early issuance of a notice of allowance is respectfully requested.

If there remain any outstanding issues, the Office is urged to call the undersigned at (301) 657-1282 (direct). No fees in addition to the fees submitted herewith are believed to be due. However, the Commissioner is authorized to charge any fee deficiencies or overpayment to the undersign's deposit account 50-3135.

Respectfully submitted,

/Joyce v. Natzmer/

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